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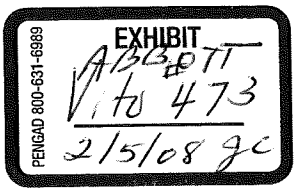

Prepared Witness Testimony

The Committee on Energy and Commerce
W.J. "Billy" Tauzin, Chairman

Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers

Subcommittee on Oversight and Investigations
Subcommittee on Health
September 21, 2001
09:30 AM
2123 Rayburn House Office Building

Mr. Thomas Connaughton

American Association of Homecare
625 Slaters Lane, Suite 200
Alexandria, VA, 22314

Mr. Chairman, my name is Tom Connaughton. I am President of the American Association for Homecare ("AAHomecare"). Our Association was formed by the merger of three national associations on February 1, 2000. We are the only national association that represents every line of service within the homecare community. Our members include providers and suppliers of home health services, durable medical equipment (DME) services and supplies, infusion and respiratory care services, and rehabilitative and assistive technologies, as well as manufacturers and state associations.

We thank you for the opportunity to discuss the Medicare reimbursement system for pharmaceuticals administered to beneficiaries by homecare providers and suppliers, in particular, home infusion therapies and inhalation therapies administered to respiratory patients. Homecare providers and suppliers save Medicare money by treating patients in the most cost-effective setting – their homes. The savings generated by treating patients at home can be dramatically cost-effective when compared to the cost of the same therapy administered in an institutional setting.

Joining me is JoAnn Lamphere (Dr.P.H.) of The Lewin Group. At the request of our association, The Lewin Group conducted a survey of providers and suppliers of inhalation and infusion therapies in order to determine the costs associated with these therapies. The Lewin Group has prepared a report analyzing the results of this survey. To our knowledge, it is the most definitive report on the subject to date. Dr. Lamphere will summarize the findings of that report and, of course, a complete copy is attached for your information.

I want to begin by making an important distinction between infusion and inhalation therapies administered to patients in their homes and conventional outpatient drugs such as pills and "patches." The key difference is that pills and patches do not require professional services to administer. An individual can consume a pill or apply a patch himself after obtaining it from a retail or "traditional" pharmacy. In contrast, infusion and inhalation therapies cannot be administered to patients at home without a complex array of professional services. These medications are provided only on the prescription of a physician and as required by regulatory, accrediting and pharmacy licensing bodies, are prepared in high-tech, sterile settings similar to those found in a hospital. These services ensure the safe and effective administration of infusion and inhalation therapy in the home.

As we begin this discussion, it is also important to note that homecare providers and suppliers are not paid separately for these important services. Medicare does not have a separate benefit for these homecare

therapies. Infusion and respiratory medications furnished to homecare patients are covered under the Medicare DME benefit. This means that the only items that are explicitly covered and reimbursed are the drugs, the equipment, and the supplies. Unlike other health care professionals, homecare providers and suppliers do not have a mechanism that reimburses the services necessary to administer the drugs in addition to the reimbursement for the drugs. By comparison, the private managed care sector has recognized the tremendous cost-savings associated with homecare and it continues to provide coverage for a growing list of home infusion and inhalation therapies. Moreover, such organizations contract with providers for extended periods of time, guarantee tremendous volume, and structure their contracts with both a fee for the drug and a per diem to assist in covering the providers' costs of services.

Inhalation Therapy

Inhalation therapy is administered to patients with respiratory disease, including, for example, chronic obstructive pulmonary disease (COPD). COPD is the fourth leading cause of death in the United States, affecting 16 million people.[1] COPD includes a number of chronic respiratory diseases such as emphysema, chronic bronchitis, and asthma. Individuals with COPD have a progressive illness. The disease can be stabilized, but it cannot be cured. Inhalation therapy is used to manage COPD throughout the course of the disease, but in the more advanced stages of COPD, other therapeutic interventions may be required.

Specifically, inhalation therapy is the process through which a drug or a combination of drugs is delivered into the airways and inhaled directly into the lungs via a device called a nebulizer. These drugs may include beta-adrenergic bronchodilators, anticholinergic bronchodilators, mast cell stabilizers, anti-

inflammatory steroids, antibiotics, and sputum liquefiers. Patients receiving inhalation therapy at home are monitored by respiratory therapists and highly trained pharmacists. Inhalation therapies reduce acute exacerbations of COPD, saving the Medicare program money in emergency room visits and inpatient stays.

Infusion Drug Therapy

Private sector insurance plans and private managed care plans increasingly have embraced home infusion drug therapy since the 1980's. Antibiotic therapy, chemotherapy, and pain management are among the spectrum of infusion therapies that are now commonly provided to patients in their homes. Currently, there are over twenty different drug therapies being offered in the home and other outpatient settings in the private sector. The private sector plans and payers typically recognize expressly and separately the professional services necessary to provide infusion drug therapy in a safe and effective manner in the home setting.

Infusion drug therapy involves primarily the administration of the drug into the body through a needle or a catheter. Typically, infusion drug therapy means that a drug is administered intravenously, but it may also apply to situations where drugs are provided through other parenteral (non-oral) routes. Generally, infusion drug therapies are used only when less invasive means of drug administration are clinically unacceptable or less effective. A team of patient service representatives, clinical pharmacists, high tech infusion nurses, and delivery and reimbursement professionals support patients and their caregivers throughout their treatment. These services are inextricably linked to the therapies and are often mandated by accrediting bodies whose standards ensure quality delivered in an alternate site setting.

Providing infusion therapies at home has several advantages over hospital-based therapy. Most patients prefer to receive such therapies at home rather than in the hospital or in a skilled nursing facility. Homecare therapy allows many patients to lead normal lives throughout the duration of the therapy; it enables terminally ill patients to spend valuable time with their families and loved ones. Also, the ability to administer these therapies in the home reduces the risk of hospital-acquired infections that are sometimes associated with prolonged in-patient stays. In most cases, the cost of infusion drug therapy when properly provided in the home is far less than the cost of such care in the hospital.

Medicare Coverage of Home Respiratory and Infusion Inhalation Therapies

It is important to note that Medicare covers very few of the infusion drug therapies when provided at home. Further, as I stated above, Medicare does not have a separate inhalation therapy benefit or a home infusion therapy benefit. Medicare coverage for these therapies in the home is found only under the DME benefit - but only when equipment such as a nebulizer or an infusion pump is necessary. The fact that coverage for these therapies is limited to the DME benefit is a very important point in understanding the homecare community's issues with drug reimbursement, because the DME benefit explicitly covers only the drugs, supplies, and equipment. There is no recognition of the professional services and other functions that are widely recognized as necessary to providing inhalation and infusion drug therapies in the home in a safe and effective manner.

The Medicare program's lack of recognition of these professional services is illogical, potentially threatening to beneficiaries, and contrary both to how clinicians define and the private sector plans cover these therapies. The clinical value and necessity of the provision of professional services to deliver inhalation and infusion therapies is reflected in various accreditation standards commonly used by private sector payers, such as the standards established by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Indeed,

private payers pay for these services as a specific component of the benefit. The Lewin Group's analysis provides a good picture of the costs involved in providing such services.

These therapies require specialized pharmacy services. Such services include the compounding of many of the drugs in a sterile setting, responding to emergencies and questions regarding therapy, and participating in the training and education of the patient (and often the patient's family). These therapies also require the services of a nurse or respiratory therapist to perform a variety of functions, including patient screening and assessment, patient training regarding administration of the pharmaceuticals, and general monitoring of the patient's health status. In the case of infusion therapy, these services also include care for the infusion site, and monitoring of the catheter exit site for signs of infection or other complications. In addition, the drug, supplies, and equipment are delivered to the patient's home often within four hours of the prescription. Patient satisfaction and other outcomes are measured and reported to accrediting organizations as part of quality improvement programs. Finally, staff, including licensed pharmacists, pharmacy technicians, respiratory therapists, and registered nurses, are on call 24 hours a day.

It is important to underscore that none of the specialized pharmacy services is covered under any other Medicare benefit. In a minority of cases, Medicare home infusion patients may meet the "homebound" requirement and qualify for the home health benefit. In such instances, the nursing services described above would be covered under that benefit. For all other Medicare Infusion Patients, the nursing services are not covered by the home health benefit.

Average Wholesale Price and Drug Pricing Issues

Much has been said about how Medicare pays for the few outpatient drugs that are covered currently. The use of the average wholesale price (AWP) as the principal basis for determining reimbursement for drugs has received much criticism recently as being an inaccurate reflector of the physicians' and pharmacists' costs for these drugs. There is little question that these criticisms are correct - if the payment "buys" drugs only. In actual fact, the drug payment calculated on the basis of AWP has been used for far more than that. With regard to inhalation and infusion therapy in the home setting, the drug payment is the only available payment mechanism for needed functions that are essential to providing good quality care. In other words, the spread between the providers and suppliers' acquisition cost and the Medicare reimbursement under Medicare Part B must cover all functions and services. The acquisition cost of the drug is only a fraction of the overall cost of caring for these patients at home.

The conclusions of the Lewin report, which Dr. Lamphere will explain in more detail, reinforce the point that the cost of the drugs represents only one small portion of the overall cost of caring for these patients in need of inhalation or infusion therapy. Indeed, the cost of goods represents 26% of total costs while direct patient care costs average 46% and indirect costs such as accreditation, information systems, and

Medicare/Medicaid regulatory compliance amount to another 25%.

In the case of infusion therapies delivered to Medicare beneficiaries, providers, and suppliers, costs exceed the revenues received under Medicare. For respiratory medications, providers and suppliers report an average margin of 9.2% after taxes, which is considerably less than the average after tax margin of 14.4% reported by companies on the S&P index for the same time period in 2000.

It is important to note that homecare providers are not engaged in the selection of a particular drug. Physicians prescribe exactly which drugs should be used. The services furnished by homecare providers and suppliers are triggered by the physician's prescription. Their jobs begin when they receive the physician's order.

Policymakers simply cannot look at drug payment as an isolated issue, separate from the other workings of a particular therapy. Reducing drug payments dramatically, without corresponding changes in other aspects of the payment methodologies, would truly strain the ability of suppliers and providers to continue to provide these drug therapies to Medicare beneficiaries. Indeed, homecare providers and suppliers are in a far more tenuous position regarding drug reimbursement than are other providers because they receive ***no payment whatsoever*** for the important functions and services. Reimbursement for drug therapies delivered in the home is tied solely to the drug supplies and equipment. There is no fee schedule for services. These necessary professional services must be recognized, and they should be reimbursed.

While we have analyzed the AWP system and possible alternatives, we have not been able to develop a recommendation for the Subcommittees for a system that accurately determines the cost of products to providers and suppliers. These costs vary so widely among providers and suppliers that it is difficult to conceive of a system that accurately accounts for all of these variables. Accordingly, we urge Congress to proceed with caution. However, if Congress contemplates changing the reimbursement system under Part B for drugs administered in the home, it is critical that it recognizes the services involved and provide a framework for reimbursing them. It is not an option, in our opinion, to limit payment and coverage strictly to what is covered under the DME benefit. If Medicare beneficiaries receive only what the DME benefit currently recognizes- the drug, supplies, and equipment (pump or nebulizer), - then the level of care for the Medicare beneficiaries will be far less than that commonly provided in the private sector. Indeed, there are questions whether there will be access for Medicare beneficiaries at all. That result would be neither fair nor clinically appropriate. Medicare beneficiaries often are less able to deal with the complexities of these technical homecare therapies than are people who are decades younger.

Recommendations

We believe that it is important to establish accurate definitions of home respiratory and infusion therapy, create quality standards based on those currently and widely used in the private sector, and establish a fee schedule that reflects all the covered components of the therapies. H.R. 2750, introduced earlier this year by Congressman Engel of New York, Congressman Rush of Illinois, Congressman Towns of New York, and Congresswoman Hart of Pennsylvania, would do exactly that for Medicare coverage of home infusion therapy. This bill would remove coverage of home infusion therapy from the DME benefit and establish a new benefit that accurately reflects how these therapies are and should be provided. If enacted, this bill will bring the Medicare program in-line with the private sector as to how these therapies are covered and defined. We believe this approach is equally appropriate for inhalation therapies provided in the home if Congress revises the reimbursement system for Medicare Part B and drugs.

Mr. Chairman, AAHomecare thanks you for the opportunity to present views on behalf of our member companies. Please do not hesitate to call upon us for additional information.

[1] See National Institutes of Health, Global Initiative For Chronic Obstructive Pulmonary Disease, April 2001; Agency for Health Care Quality Research Evidence Based Practice Guidelines, Management of Acute Exacerbations of Chronic Obstructive Pulmonary Disease.

The Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515
(202) 225-2927
Feedback